DECLARATION OF CONFORMITY

No. AFC-DOC-M20210120-02

Manufacturer: ARKRAY Factory, Inc.
Address: 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

European Representative: ARKRAY Europe, B.V.
Address: Prof. J.H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS

Object of the declaration:
GLUCOCARD S Kit * (Serial No.: AAE200008001 and subsequent numbers)
-Components: ①GLUCOCARD S
②GLUCOCARD S Test Strips
③Lancing Device TD-5010*
④NANOLET™ Lancet*
** For more detail, refer to the EC Declaration of Conformity respectively*

<IVD Directive>

Classification: LIST B According to Annex II of the Directive 98/79/EC
Conformity Assessment Route: Annex IV excluding (4,6) Applied (Directive 98/79/EC concerning IVD)

Product Category:
GMDN code: 62537, Glucose monitoring system IVD, home-use

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documents are retained on the premises of the manufacturer.

The object of the declaration described above is in conformity with the requirements of the following documents: EN ISO 13485: 2016, EN ISO 14971: 2012 and EN ISO 15197: 2015.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 · 80339 München · Germany
Identification No. 0123

EC Certificate No.: V1 027591 0045 Rev. 01

<RoHS Directive>

We also declare that the above-mentioned products "GLUCOCARD S" and "GLUCOCARD S Test Strips" meet the provisions of the Council Directive 2011/65/EU for RoHS directive and are in conformity with the requirements of the documents, EN 50581:2012. All supporting documents are retained on the premises of the manufacturer.

Shiga, JAPAN

2021-01-22
Place and date

Shuzo Joko
Shuzo Joko
Director of Quality Division
ARKRAY Factory, Inc.

DECLARATION OF CONFORMITY

No. AFC-DOC-M20210120-04

Manufacturer: ARKRAY Factory, Inc.
Address: 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

European Representative: ARKRAY Europe, B.V.
Address: Prof. J.H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS

Object of the declaration:
GLUCOCARD S onyx Kit *
(Serial No.: To be determined)
-Components: 1. GLUCOCARD S onyx
2. GLUCOCARD S Test Strips
3. Lancing Device TD-5010*
4. NANOLET™ Lancet*

** For more detail, refer to the EC Declaration of Conformity respectively*

<IVD Directive>

Classification: LIST B According to Annex II of the Directive 98/79/EC
Conformity Assessment Route: Annex IV excluding (4,6) Applied (Directive 98/79/EC concerning IVD)

Product Category:
GMDN code: 62537, Glucose monitoring system IVD, home-use

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documents are retained on the premises of the manufacturer.

The object of the declaration described above is in conformity with the requirements of the following documents: EN ISO 13485: 2016, EN ISO 14971: 2012 and EN ISO 15197: 2015.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 · 80339 München · Germany
Identification No. 0123

EC Certificate No.: V1 027591 0045 Rev. 01

<RoHS Directive>

We also declare that the above-mentioned products "GLUCOCARD S onyx" and "GLUCOCARD S Test Strips" meet the provisions of the Council Directive 2011/65/EU for RoHS directive and are in conformity with the requirements of the documents, EN 50581:2012. All supporting documents are retained on the premises of the manufacturer.

Shiga, JAPAN

2021-01-22
Place and date

Shuzo Joko
Shuzo Joko
Director of Quality Division
ARKRAY Factory, Inc.

DECLARATION OF CONFORMITY

No. AFC-DOC-M20210120-05

Manufacturer: ARKRAY Factory, Inc.
Address: 1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

European Representative: ARKRAY Europe, B.V.
Address: Prof. J.H. Bavincklaan 2, 1183 AT Amstelveen, THE NETHERLANDS

Object of the declaration:
GLUCOCARD X-METER Kit *
-Components: 1. GLUCOCARD X-METER (Serial No.: To be determined)
2. GLUCOCARD X-SENSOR
3. Lancing Device TD-5010*
4. NANOLET™ Lancet*

** For more detail, refer to the EC Declaration of Conformity respectively*

<IVD Directive>

Classification: LIST B According to Annex II of the Directive 98/79/EC
Conformity Assessment Route: Annex IV excluding (4,6) Applied (Directive 98/79/EC concerning IVD)

Product Category:
GMDN code: 62537, Glucose monitoring system IVD, home-use

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documents are retained on the premises of the manufacturer.

The object of the declaration described above is in conformity with the requirements of the following documents: EN ISO 13485: 2016, EN ISO 14971: 2012 and EN ISO 15197: 2015.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65 · 80339 München · Germany
Identification No. 0123

EC Certificate No.: V1 027591 0045 Rev. 01

<RoHS Directive>

We also declare that the above-mentioned products "GLUCOCARD X-METER" and "GLUCOCARD X-SENSOR" meet the provisions of the Council Directive 2011/65/EU for RoHS directive and are in conformity with the requirements of the documents, EN 50581:2012. All supporting documents are retained on the premises of the manufacturer.

Shiga, JAPAN

2021-01-22
Place and date

Shuzo Joko
Shuzo Joko
Director of Quality Division
ARKRAY Factory, Inc.

Form number/ B-IaAAA-18001-03 Ver.2

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 027591 0045 Rev. 01

Manufacturer:

ARKRAY Factory, Inc.
1480 Koji, Konan-cho
Koka-shi, Shiga 520-3306
JAPAN

Product Category(ies): **Blood glucose measuring systems for self testing and other systems for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 027591 0045 Rev. 01

Report no.: **JN1574622**

Valid from: **2020-11-24**
Valid until: **2024-05-26**

Date, **2020-11-24**

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 027591 0045 Rev. 01

Model(s):

GLUCOCARD:
Self Monitoring Blood Glucose System,
Lactate Pro:
Lactate analyzer for self testing

Facility(ies):

ARKRAY Factory, Inc.
1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

ARKRAY, Inc.
Yousuien-nai, 59 Gansuin-cho, Kamigyo-ku, Kyoto 602-0008, JAPAN

ARKRAY Industry West, Inc.
Main Avenue Cor. 3rd Street, Cavite Economic Zone, Rosario, Cavite 4106, PHILIPPINES

-/-

Shuzo Joko 2021-04-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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